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A Comparison of Treatment Strategies for Hypoplastic Left Heart Syndrome Using Decision Analysis

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OBJECTIVES We sought to identify the optimal treatment strategy for hypoplastic left heart syndrome (HLHS).

BACKGROUND Surgical treatment of HLHS involves either transplantation (Tx) or staged palliation of the native heart. Identifying the best treatment for HLHS requires integrating individual patient risk factors and center-specific data.

METHODS Decision analysis is a modeling technique used to compare six strategies: staged surgery; Tx; stage 1 surgery as an interim to Tx; and listing for transplant for one, two, or three months before performing staged surgery if a donor is unavailable. Probabilities were derived from current literature and a dataset of 231 patients with HLHS born between 1989 and 1994. The goal was to maximize first-year survival.

RESULTS If a donor is available within one month, Tx is the optimal choice, given baseline probabilities; if no donor is found by the end of one month, stage 1 surgery should be performed. When survival and organ donation probabilities were varied, staged surgery was the optimal choice for centers with organ donation rates <10% in three months and with stage 1 mortality <20%. Waiting one month on the transplant list optimized survival when the three-month organ donation rate was ≥30%. Performing stage 1 surgery before listing, or performing stage 1 surgery after an unsuccessful two- or three-month wait for transplant, were almost never optimal choices.

CONCLUSIONS The best strategy for centers that treat patients with HLHS should be guided by local organ availability, stage 1 surgical mortality and patient risk factors. (J Am Coll Cardiol 2001;38: 1181–7) © 2001 by the American College of Cardiology

Parents and caregivers of children with hypoplastic left heart syndrome (HLHS) are faced with difficult choices from the moment the diagnosis is made. Some physicians may recommend comfort care (1), but most will recommend surgical treatment of the defect. Although studies have shown transplantation (Tx) to have better one- and five-year survival than staged surgery (2,3), heart donors are difficult to find. Infants with HLHS could wait six months or more on the transplant list, with longer waiting time generating an increased risk of death on the waiting list, removal from the list for organ failure and possibly increased risk of death even after a successful Tx (4–6). If the infant never receives a donor heart and a stage 1 procedure is performed after a wait, the child may have an increased mortality risk after stage 1 surgery attributable to the wait (5,7,8). Identifying the best treatment strategy for a child with HLHS requires integrating individual risk factors with center-specific data. The wide variation in decision making among caregivers of these children reveals how daunting this task is.

Decision analysis provides a framework for quantitatively identifying the treatment strategy that, on average, has the highest chance of success (9,10). Decision analysis is a modeling technique that structures the problem into choices, chance events and outcome measures. It is especially useful for comparing strategies that are not in current practice with those that are well established (11). Furthermore, by showing how changes in probabilities influence the optimal treatment strategy, decision analysis helps focus attention on which probabilities are important to the decision.

The techniques of decision analysis were used to compare surgical options for the treatment of HLHS so as to maximize one-year survival. The goal was to identify whether one treatment strategy optimized survival in all cases, or whether the optimal strategy changed depending on characteristics of patients or centers. The analysis used

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Abbreviations and Acronyms
HLHS = hypoplastic left heart syndrome
Tx = transplantation

data from the literature and from values obtained in a dataset of 231 patients with HLHS treated at four surgical centers between 1989 and 1994 (3).

METHODS

Clinical strategies/decision tree. Treatment strategies that are well established were compared with new possibilities for treatment (Table 1). The options were to complete staged surgery; to use stage 1 surgery as an interim procedure to Tx; to list the patient for Tx and perform staged surgery if no donor is found in a specified time; and to wait for a donor heart without recourse to staged surgery (Fig. 1). Strategies known to create lower survival for most babies with HLHS, such as not performing stage 2 surgery after a stage 1 procedure (12,13), were not included. The software used was DATA 3.0 (TreeAge Software, Inc., Williamstown, Massachusetts).

Outcome. We sought to maximize survival at one year. Infants with HLHS who survive the first year are highly likely to survive five years (2,3).

Probabilities. When possible, baseline probabilities and sensitivity analysis ranges (Table 2) were obtained from literature reports of patients with HLHS born after 1989 (2,3,7,12,14–23). When no current information was available, probabilities were obtained from older publications detailing HLHS treatment (5,24), from the general pediatric transplant literature (25–27), or from a dataset of 231 patients with HLHS born between 1989 and 1994, whose major survival results have been published (3). Decision-tree values were assigned using the most recent information with the largest number of cases reported. Where appropriate, published survival data were recalculated to yield intention-to-treat data, comparable across studies. For example, one report (5) cited the pretransplant mortality for patients with HLHS as 19%; including patients who were unlisted increased the waiting-list mortality to 25%. Another report (23) calculated stage 1 survival as 86%; for purposes of comparability, including patients older than one month at surgery lowered stage 1 survival to 83%.

Directly related probabilities were linked in the tree by assigning multiples of the original probability to the related probability. For example, the probability of receiving a donor increased over the first three months of waiting, then leveled off (Fig. 2) in our dataset. The assigned values of this probability at two (0.58) and three (0.68) months were fractional multiples of the one-month value (0.38).

Assumptions. Infants with HLHS were assumed to be eligible for any surgical strategy on the decision tree. Once infants entered a treatment strategy, they stayed in that strategy. Probabilities obtained from the HLHS dataset and from literature reviews were assumed to be representative of outcomes for HLHS surgical treatment. Stage 1 mortality encompassed all deaths between the first operation and the second operation. Waiting on the transplant list was assumed to affect only mortality after a subsequent stage 1 surgery, and not stage 2 mortality. In our dataset all patients in the Tx strategy either received a transplant or died by six months of age; thus, probabilities of waiting indefinitely until transplant were equated with values for a six-month wait.

Sensitivity analysis. Sensitivity analysis is a method of varying probabilities over a defined range to determine how the optimal choice would change if the value of a chance event changed. Sensitivity analysis can be performed on individual probabilities (one-way sensitivity analysis) or performed by varying two probabilities at the same time (two-way sensitivity analysis). One-way sensitivity analysis was performed for each probability in the decision tree, and the values at which the optimal strategy changed (threshold values) were identified. Two-way sensitivity analyses were performed for all probabilities.

RESULTS

The comparison of treatment strategies for HLHS in Figure 1 showed that performing Tx within one month, and

Table 1. Treatment Strategies for Hypoplastic Left Heart Syndrome Considered at Diagnosis

Name	Description of Strategy
Staged surgery	Stage 1 and stage 2 surgeries are performed.
Stage 1, then list	Stage 1 is performed and the patient is listed for transplantation. Patient receives a transplant if an organ is available.
List, wait 1 month	If an organ is found within one month, the patient receives a transplant. If no organ is found in that time, Stage 1 is performed, followed by stage 2.
List, wait 2 months	If an organ is found within two months, the patient receives a transplant. If no organ is found in that time, Stage 1 is performed, followed by stage 2.
List, wait 3 months	If an organ is found within three months, the patient receives a transplant. If no organ is found in that time, Stage 1 is performed, followed by stage 2.
List, wait until transplant	Patient waits indefinitely until an organ is available.

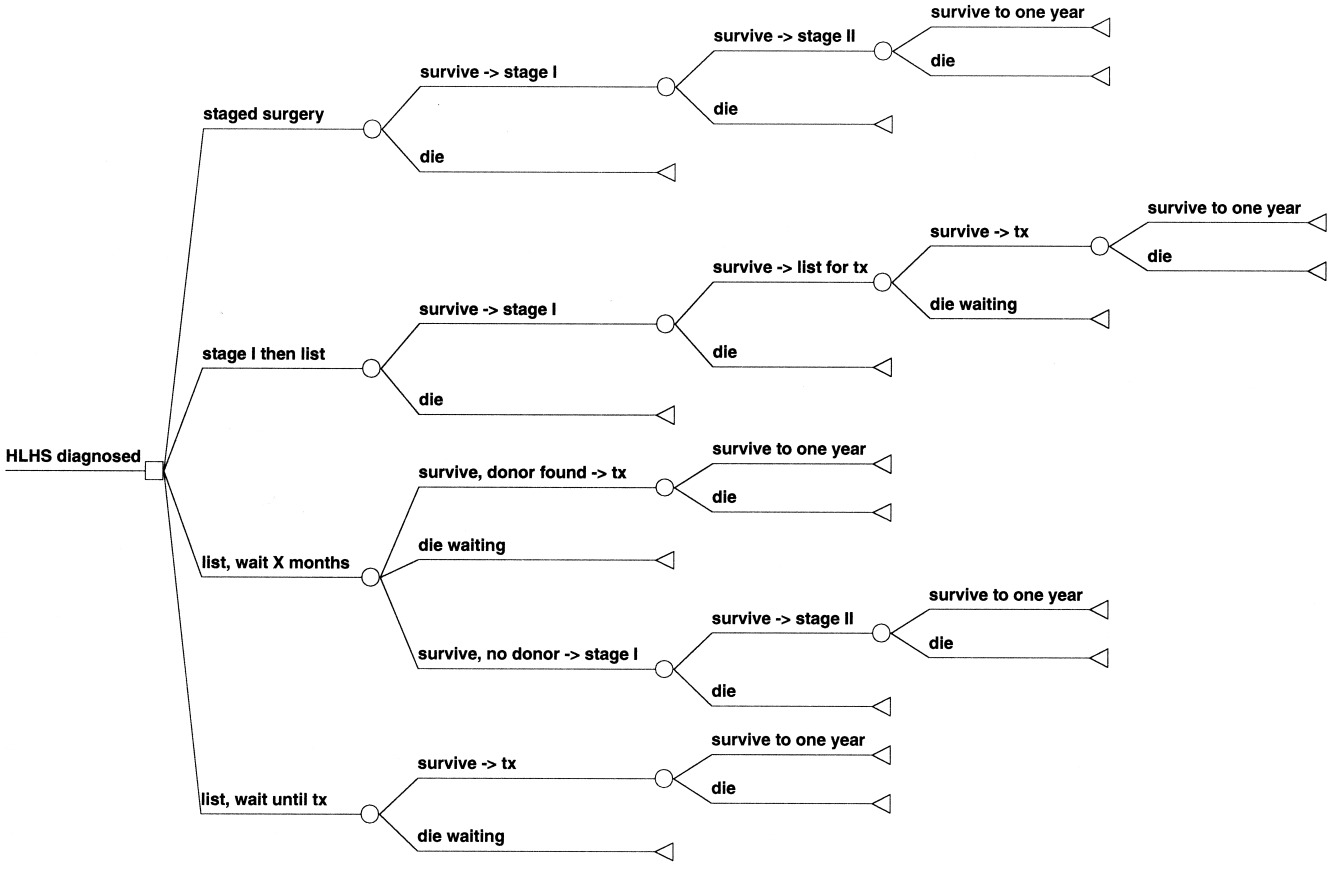

Figure 1. The decision tree comparing surgical treatment strategies for hypoplastic left heart syndrome (HLHS) is shown. Once HLHS is diagnosed, a decision **(open square)** is made as to which treatment strategy to undertake. After the strategy is decided, events **(open circles)** occur, with defined probabilities for mutually exclusive outcomes, "survive" or "die." Survival to surgery or to listing for transplantation (Tx) is not certain, and a probability is associated with that survival. All babies surviving to surgery are assumed to receive that treatment as planned. The outcome measure was survival to one year.

then if no donor is found performing staged surgery, proved the optimal choice for survival at one year, given the parameters in Table 2. The expected one-year survival of "list 1 month" was 59%, slightly higher than the expected survival for "list 2 months" and "list 3 months" of 56%, and for "list until Tx" of 58%. For "staged surgery," expected one-year survival was 49%; and for "stage 1 then list," expected survival was 32%.

One-way sensitivity analyses were performed on each probability to allow it to vary across a range. These sensitivity analyses (Fig. 3) revealed probability thresholds at which the optimal choice changed from one strategy to another. Factors whose values changed the optimal treatment strategy were stage 1 mortality, stage 2 mortality, the three-month organ donation rate and mortality after Tx. By one-way analysis, a center that finds 80% of its listed infants with HLHS a donor organ in three months will have the best survival outcomes by waiting indefinitely for a donor, whereas a center with a three-month organ donation rate $<8\%$ would have the highest survival by offering staged surgery at the outset.

In two-way sensitivity analyses, staged surgery, listing for one month before performing stage 1 surgery, and listing indefinitely until Tx were the strategies that generated the highest survival in almost all analyses. The strategy of performing stage 1 surgery as an interim procedure to Tx never generated a higher survival than the other strategies. Waiting two or three months for Tx before performing stage 1 surgery also had worse one-year survival in almost all scenarios, due to the designation of rapidly rising mortality after these waits and stage 1 surgery (Table 2). The two-way sensitivity analysis varying organ availability and combined stage 1 mortality is presented in Figure 4; these two probabilities were the most important ones in the decision tree. For organ availability $<10\%$ in three months, or for a combined stage 1 mortality of $<20\%$, staged surgery was the best option. For organ availability $>30\%$ to 40% in three months, listing the infant for Tx for at least one month optimized survival. If stage 1 mortality and the three-month organ donation rates were both 30%, values lying on a dividing line between strategies, the staged surgical strategy and the strategy of listing for one month generated equivalent survival outcomes.

DISCUSSION

This study combined relevant information in a structured way to improve decision making for the surgical manage-

Table 2. Probabilities Used in the Decision Tree

Probability	Decision Tree Value	Reference	N	Other Published Values	Other References	Sensitivity Analysis Range
Mortality before stage 1	0.01	Jacobs, 1998	253	0.02–0.04	(3,23)	0–0.30
Combined stage 1 mortality	0.48	Jacobs, 1998	250	0.17–0.50	(2,3,7,14,15,18–22)	0–0.80
For 1-month wait	0.50	Jenkins, 2000	7	0.50	(2)	
For 2-month wait	0.71	Iannettoni, 1994	7			
For 3-month wait	0.85	*				
Stage 2 mortality	0.04	Williams, 2000	106	0.00–0.17	(2,3,12,17–20)	0–0.50
Finding a donor after stage 1 surgery	0.75	Bove, 1991	4	0.75–1.00		0–1.00
Mortality after stage 1 and transplant	0.17	Jenkins, 2000	4	0–0.67	(21,24,26)	0–1.00
Organ donation in 1 month	0.38	Jenkins, 2000	112	0.23–0.53	(2,5,25)	
In 2 months	0.58	Jenkins, 2000	112	0.46–0.77	(2,25)	
In 3 months	0.64	Jenkins, 2000	112	0.67–0.80	(2,25)	0–0.90
In indefinite wait	0.70	Jenkins, 2000	112	0.45–0.96	(2,5,21,25)	
Transplant mortality for 1-month wait	0.17	Jenkins, 2000	44	0–0.17	(5,25)	
For 2-month wait	0.17	Jenkins, 2000	67	0–0.22	(5,25)	
For 3-month wait	0.17	Jenkins, 2000	72	0–0.29	(5,25)	0–0.75
For indefinite wait	0.17	Jenkins, 2000	78	0–0.43	(5,25–27)	
Waiting list mortality in 1 month	0.04	Jenkins, 2000	112	0.02–0.10	(2,25)	
In 2 months	0.14	Jenkins, 2000	112	0.04–0.16	(2,25)	
In 3 months	0.17	Jenkins, 2000	112	0.04–0.18	(2,25)	0–0.50
In indefinite wait	0.29	Jenkins, 2000	112	0.04–0.55	(2,5,25)	

*No data were available for this probability; it was assigned based on related published values.

ment of hypoplastic left heart syndrome. In this decision analysis, under baseline probabilities, the best treatment strategy for patients with HLHS involved performing Tx within one month, and then if no donor is found performing staged surgery. To optimize survival outcomes while accounting for the trade-off between organ availability and stage 1 mortality rates, we varied these probabilities at the same time in a two-way sensitivity analysis. Figure 4 is essentially a decision-making algorithm using these two probabilities to determine the optimal strategy. It showed that for low organ availability (<10% in three months) or for a low combined stage 1 mortality (<20%), staged surgery was the best option. For a center with moderate organ availability (>30% to 40% in three months), listing the infant for Tx for at least one month optimized survival. The strategies with less favorable survival were those of performing staged surgery after an unsuccessful two- to three-month wait for a donor and of performing stage 1 surgery and then listing the patient for Tx.

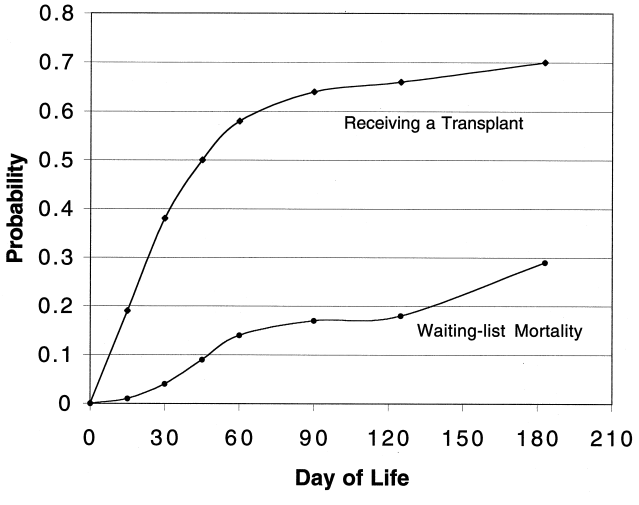

Figure 2. The probabilities of receiving a transplant and of waiting-list mortality, depicted on the **vertical axis**, are shown as a function of age in days on the **horizontal axis**. Both probabilities increase with time on the waiting list. Data are derived from the hypoplastic left heart syndrome dataset (3).

A center's specific organ donation pattern and survival outcomes can inform the surgical decision, as above, to optimize survival for an "average" patient with HLHS. Patient-specific risk factors for mortality and organ availability are also highly applicable to this decision analysis. Although many preoperative characteristics of patients with HLHS have been implicated as increasing mortality risk—for staged surgery: size of the descending or ascending aorta; aortic and mitral atresia, obstruction to pulmonary venous return, noncardiac congenital anomalies, age >1 month at surgery, lower birth weight, high creatinine and acidosis (2,3,8,20,21,23,28); for Tx: previous sternotomy, nonidentical blood type, specific recipient blood types, high creatinine, restrictive atrial septal defect and lower birth weight (3,26,29)—none have been consistent risk factors for mortality across all studies. When consensus is reached on risk factors for mortality in HLHS, this information can be used with Figure 4 to determine the strategy with the highest expected survival for an individual patient. For instance, if one infant with HLHS had an expected stage 1 mortality of 20% at a center with moderate donor availability, staged surgery would optimize that infant's survival.

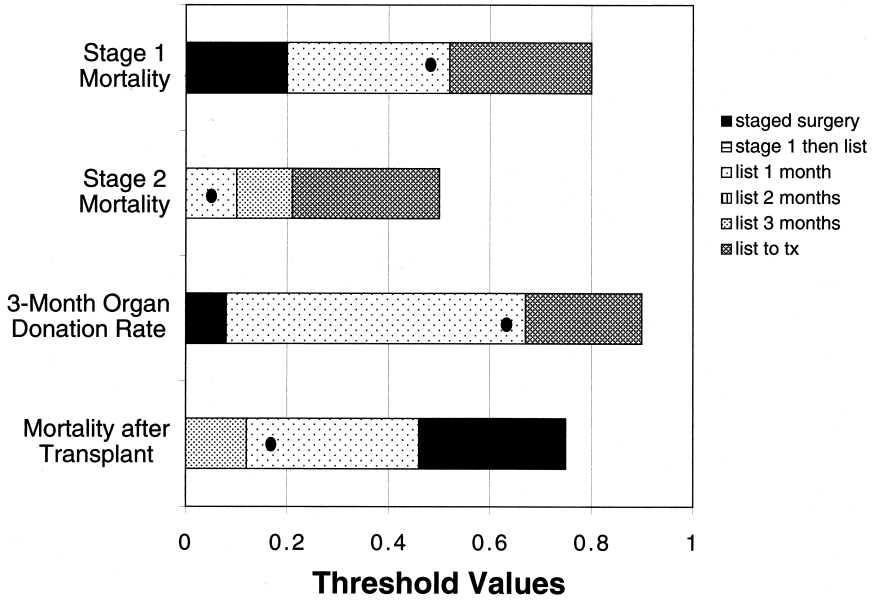

Figure 3. Threshold values of one-way sensitivity analyses, which vary each probability separately, are shown. A threshold value is the value of the probability at which the optimal strategy changed. Thresholds were obtained in the probabilities (shown along the **vertical axis**) for stage 1 mortality, stage 2 mortality, organ availability and mortality after transplantation. Therefore, these probabilities are most important to the decision. The optimal strategy for particular values of each probability is shown by the pattern corresponding to the legend **(right)**. For example, a center with a combined stage 1 mortality of 15% would optimize survival by offering staged surgery, whereas a center with a stage 1 mortality of 30% would optimize survival by listing the patient for one month before performing stage 1 surgery if no donor is found. No thresholds were found for other probabilities. **Black dots** indicate the baseline values in the decision tree. The baseline values all lie in probability ranges that favor listing the patient for one month. Tx = transplantation.

However, if another infant with HLHS had an expected stage 1 mortality of 80%, and the center had moderate donor availability, listing the infant for one month before proceeding to staged surgery would optimize the infant's survival.

Study limitations. A possible limitation of using current literature values is that the reports may reflect only best practice or may not be representative of smaller-volume centers. However, varying the probabilities across a wide range in sensitivity analyses allows the results to be generalizable over time and across centers. In essence, unpublished results are represented in the sensitivity analyses. Another limitation is that the values assigned for stage 1 mortality after a two- or three-month wait were based on scant data. We are unlikely to obtain any more information in that regard as these strategies are not in current practice.

Future directions. Longer-term outcome data for children with HLHS are becoming available. The survival curve for infant transplant recipients with congenital heart disease continues to decline at the rate of about 1% annually after the first year (25). For the Fontan procedure, those who survive the first year after the operation have a mortality <1% per year (13,30,31). As more information becomes available about outcomes of the treatment strategies for HLHS, this decision analysis can be refined. The analysis can also be used to understand how to optimize quality of life for patients with HLHS as this information becomes available.

Conclusions. This comparison of six treatment strategies for HLHS determined that: 1) staged surgery, and 2) performing transplantation within one month, and then if no donor is found performing staged surgery, were the strategies likely to optimize one-year survival at centers and for patients with average stage 1 mortality and organ availability rates. The local probability of organ donation and of stage 1 mortality influenced which strategy optimized one-year survival. An individual patient's predicted mortality risk and predicted organ availability will also influence the optimal surgical choice. This decision analysis can help inform the surgical decision for centers that care for patients with HLHS to determine the treatment strategy with the highest expected one-year survival.

Implications. A strength of decision analysis is its identification of important probabilities, showing where more information is needed, and where improvements are likely to have the most impact. Figure 3 identifies the probabilities that matter most: combined stage 1 mortality, stage 2 mortality to one year, the three-month organ donation rate and mortality after Tx. Improvements in survival and organ accrual may result in practice changes at some centers.

This decision analysis can be helpful for centers that offer both treatment strategies and for those that concentrate on a single strategy. A center offering both surgical options can use Figure 4 to determine the best treatment strategy by determining their stage 1 mortality and organ donation rates. A center that offers a single surgical option can also

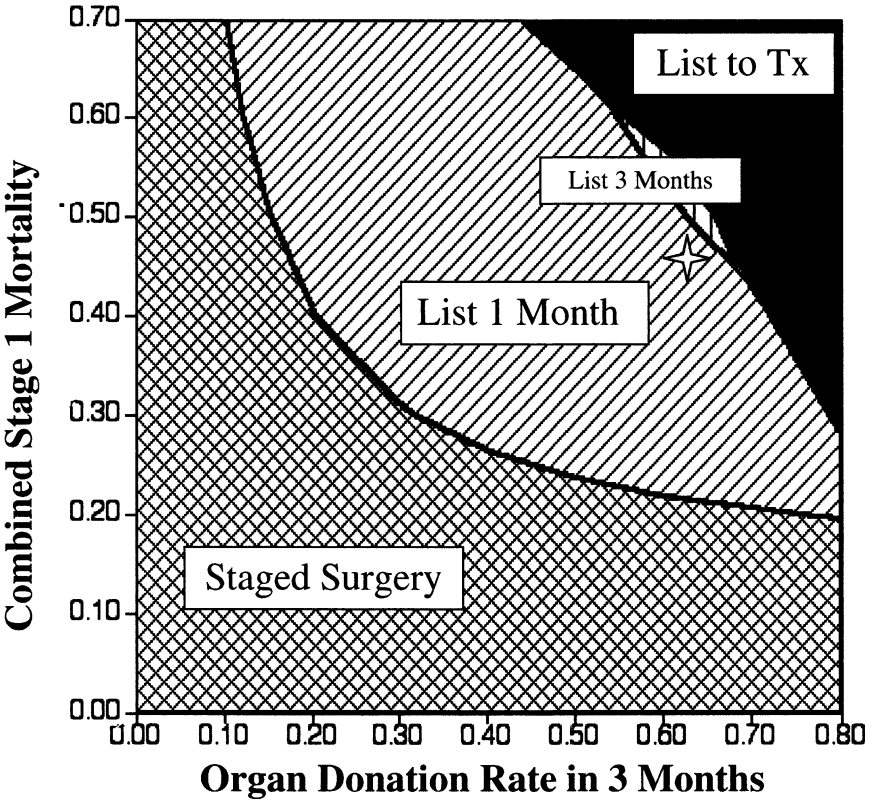

Figure 4. Two-way sensitivity analysis shows how the optimal strategy changes as the probability of organ donation in three months **(horizontal axis)** and the probability of combined stage 1 mortality **(vertical axis)** are varied. All other probabilities are retained at baseline, as in Table 2. Strategies producing optimal survival at different values of organ availability and stage 1 mortality were: 1) Staged Surgery; 2) list for one month then perform stage 1 surgery if no donor is found (List 1 Month); 3) list for three months then perform stage 1 surgery if no donor is found (List 3 Months); and 4) list indefinitely until a donor is found (List to Tx). For example, if stage 1 mortality was <20%, staged surgery was the optimal choice. With a moderate to high organ availability (more than 30% in three months) listing for transplantation (Tx) for one month or more would provide the highest survival. The **star** indicates the decision-tree baseline probabilities of organ donation in three months, 0.64; and stage 1 mortality, 0.48.

use Figure 4 to determine the optimal treatment strategy. It is logical to assume that a center performing staged surgery exclusively has a very low organ donation rate; therefore, by Figure 4 the staged surgical strategy gives the highest likelihood of survival at that center. A center that performs Tx exclusively usually has a high organ donation rate and/or a high staged surgical mortality; until those factors are modified, the Tx strategy will likely optimize survival at that center.

We recognize that no hospital operates in a vacuum. Should parents choose a surgical strategy with suboptimal survival outcomes at a particular center, referral to a different center may improve the infant's survival chances. Although parents may choose to have the surgery at a convenient center, consideration could be made to refer to a center with significantly better survival outcomes for the procedure of choice.

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